





## PROJECT COMPLETION SHEET

**PROJECT TITLE: Workflow Process Mapping for Joint Reviews** 

**GOAL/OBJECTIVE:** To improve the efficiency of the submission process for joint reviews, PMRA

and EPA proposed to develop a harmonized process that maximized the review and committee capabilities in both countries while minimizing differences that

could impact the delivery of review decisions.

## **BACKGROUND:**

PMRA and EPA have distinctly different submission processes. However, to efficiently deliver joint reviews, SOPs had to be developed such that each country could fit their scientific review times and their own committee work into the joint process while maintaining agreed upon timelines for the joint reviews. Joint review work under pilot SOPs indicated numerous areas that needed mitigation. It was agreed that a process mapping project be initiated under NAFTA to help resolve or diminish the difficulties arising out of different submission processing in each country.

## **OUTPUT/RESULTS:**

A joint session was held among senior EPA and PMRA managers from the various reviewing sectors. Each country contributed a detailed mapping of their review processes. Detailed examination of areas of differences and similarities ensued. Differences were clearly defined and where possible, resolved to enhance the joint review process. The need for improved communications was evident. The original SOPs were modified in numerous areas to better accommodate both the PMRA and EPA submission processes and minimize the differences to facilitate a better joint review process. Both countries are currently using the revised SOPs in the joint review work and both have introduced a heightened level of communication that is mutually beneficial. This project is now being managed under the Joint Review Subcommittee.